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Research Governance Framework

Research is essential to the successful promotion of health and well-being. Many of the key advances in the last century have depended on research, and health and social care professionals and the public they serve are increasingly looking to research for further improvements.

This country is fortunate to be able to draw upon a wide range of research within the health and social care systems. Most of this is conducted to high scientific and ethical standards. However, recent events have made us all painfully aware that research can cause real distress when things go wrong. The proper governance of research is essential to ensure that the public can have confidence in, and benefit from, health and social care research.

This Research Governance Framework reflects a wide range of discussions with the NHS and all the Department of Health's partners in health and social care research. We have considered carefully the responses to our earlier consultation and the issues raised in meetings with stakeholders.

I am grateful to all who have helped us with this important task. We now need to continue to work together to ensure that this Research Governance Framework for Health and Social Care is implemented successfully. In this way, we can provide the public with the reassurance it has the right to expect, and ensure that we can continue to reap the benefits of research.

Lord Hunt of Kings Heath

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This document builds on a range of earlier published work and draws extensively on the following documents:

The NHS Plan	2000
Research and Development for a First Class Service – R&D Funding in the New NHS	2000
An Organisation with a Memory – Report of an expert group on learning from adverse events in the NHS	2000
A First Class Service: Quality in the New NHS	1998
Clinical Governance – Quality in the New NHS	1998
The New NHS: Modern and Dependable	1997
A Quality Strategy for Social Care	2000
Modernising Social Services	1998
All the above are available on www.doh.gov.uk	
Valuing Diversity - Equality and Diversity in Policy Making	2000
Diversity in the Civil Service/Public Service www.cabinet-office.gov.uk	2000
OST Guidelines on Use of Scientific Advice in Policy Making http://www.dti.gov.uk/ost/ostbusiness/index_policy_making_old.htm	2000
MRC Guidelines for Good Clinical Practice in Clinical Trials http://www.mrc.ac.uk	1998

Research Governance

- Sets Standards
- Defines mechanisms to deliver standards
- Describes monitoring and assessment arrangements
- Improves research quality and safeguards the public by:
 - Enhancing ethical and scientific quality
 - Promoting good practice
 - Reducing adverse incidents and ensuring lessons are learned
 - Preventing poor performance and misconduct
- Is for all those who:
 - Participate in research
 - Host research in their organisation
 - Fund research proposals or infrastructure
 - Manage research
 - Undertake research
- Is for managers and staff, in all professional groups, no matter how senior or junior.

1. Purpose and Scope

- 1.1 The Government is committed to enhancing the contribution of research to health and social care, and to the partnership between services and science. Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.
- 1.2 This document sets out a framework for the governance of research in health and social care. The standards in this framework apply to all research which relates to the responsibilities of the Secretary of State for Health - that is research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care services that might have an impact on the quality of those services. This includes clinical and non-clinical research, research undertaken by NHS staff using NHS resources, and research undertaken by industry, the charities, the research councils and universities within the health and social care systems.
- 1.3 The framework is offered as a model for the governance of research in other areas where poor practice could have a direct impact on the health or well-being of the public.
- 1.4 The framework is of direct relevance to all those who host, conduct, participate in, fund and manage health and social care research. It is not restricted to principal investigators, managers or to any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the proper conduct of research. Participants in research and the public in general can also help to ensure that standards are understood and met.

- 1.5 This framework seeks to promote improvements in research quality across the board. As with clinical governance and best value in social care, research governance involves bringing general performance up to that of those at the leading edge. The framework provides a context for the encouragement of creative and innovative research and for the effective transfer of learning, technology and best practice to improve care.
- 1.6 The framework also aims to prevent poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified. Achievement of these aims, drawing on the work of the Chief Medical Officer's expert group on learning from adverse events¹, will promote good practice, enhance the ethical and scientific quality of research and safeguard the public.
- 1.7 Health and social care generate and draw upon a wide range of innovative work and ideas from professionals, organisations and the public. Services must promote innovation and its benefits whilst protecting participants from risk and waste. Innovation embraces a much wider range of activities than those managed formally as research. Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.
- 1.8 This document sets out the responsibilities and standards that must be applied to work managed within the formal research context. Other documents on clinical governance and on quality in the NHS and social care set out standards and systems for assuring the quality of innovative work in non-research contexts.
- 1.9 In common with other quality assurance and governance systems, this research governance framework describes:
- arrangements to define and communicate clear quality standards;
 - delivery mechanisms to ensure that these standards are met, and
 - arrangements to monitor quality and assess adherence to standards nationally.
- 1.10 Recent enquiries into adverse incidents relating to research have criticised the lack of clarity in relation to responsibilities and accountabilities for research in health and social care. This is of particular importance, given the very wide range of individuals and organisations that can be involved.

1 An Organisation with a Memory – Report of an expert group on learning from adverse events in the NHS, 2000

The framework pays particular attention to clarifying responsibilities and accountabilities.

1.11 Listed are some of the individuals and organisations involved in health and social care research:

- Patients/users, their relatives and organisations representing them.
- The public.
- Research workers.
- Universities.
- Research charities.
- Research councils.
- Health and social care professionals and professional organisations.
- Health and social care organisations.
- Local authorities.
- The pharmaceutical and other industries.
- Department of Health.

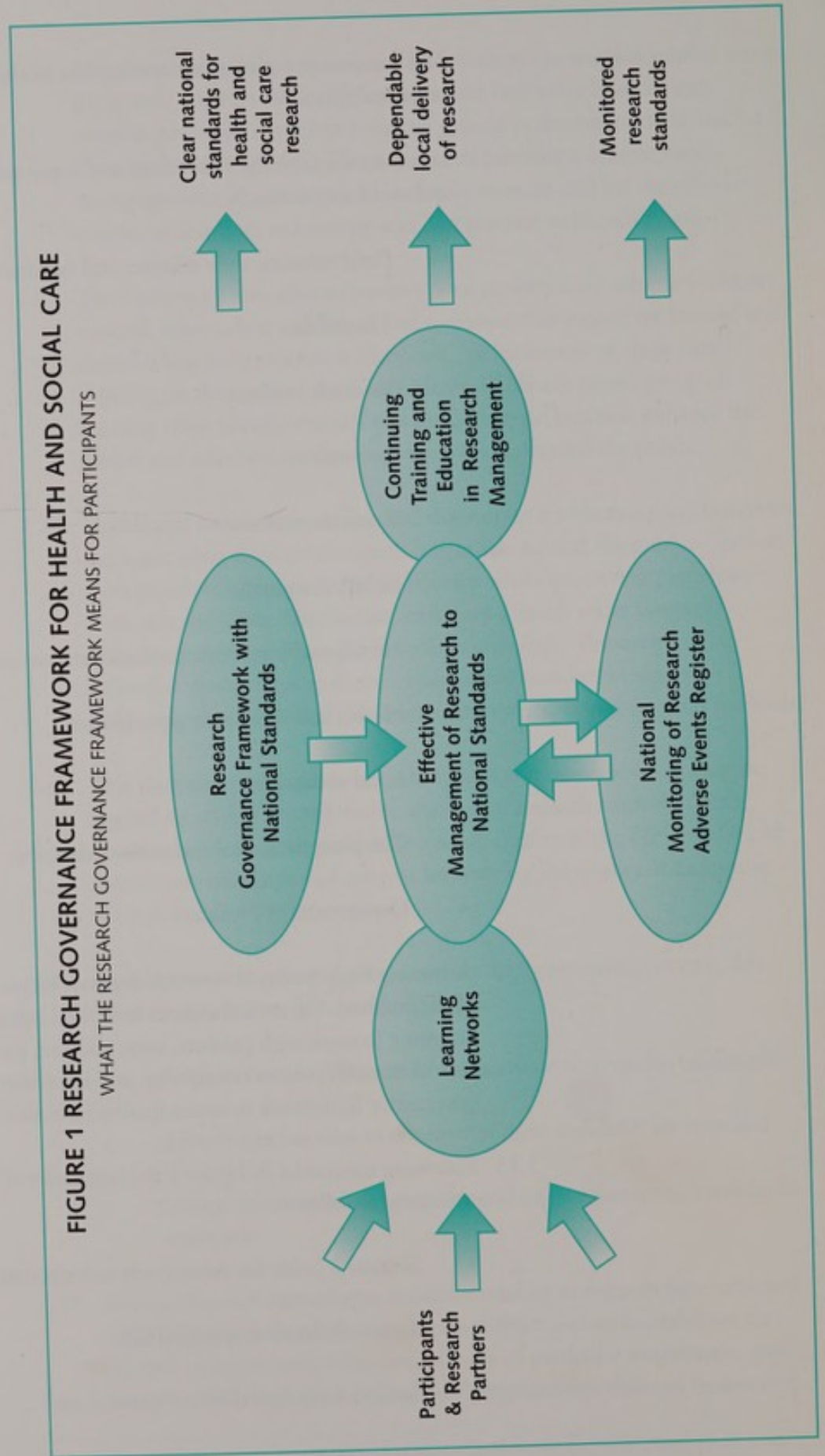
1.12 Achieving high quality in research depends on co-operation between all those involved. Figure 1 illustrates how the Department of Health will continue to work with patients, users and care professionals, the public and its research partners to develop and implement this research governance framework to assure quality in health and social care research.

1.13 Following the model in Figure 1 the remainder of this document is structured as follows:

- Section 2 (with the Annex) sets out standards.
- Section 3 details responsibilities.
- Section 4 outlines delivery systems, and
- Section 5 describes local and national monitoring systems.

FIGURE 1 RESEARCH GOVERNANCE FRAMEWORK FOR HEALTH AND SOCIAL CARE

WHAT THE RESEARCH GOVERNANCE FRAMEWORK MEANS FOR PARTICIPANTS



2. Standards

2.1 Introduction

2.1.1 Clinical governance aims to continually improve the overall standards of clinical care in the NHS and to reduce unacceptable variations in clinical practice. A comparable strategy is in place to improve the quality of social care services. Correspondingly, research governance is aimed at continuous improvement of standards and the reduction of unacceptable variations in research practice across health and social care.

2.1.2 Standards for research governance are set out in the Annex and include legislative requirements, Department of Health requirements and other helpful guidance produced from a variety of established sources. Professional judgement is necessarily involved in the interpretation of many aspects of the guidance. Quality in research therefore depends on those responsible being appropriately qualified with the relevant skills and experience to use their professional judgement effectively in the delivery of dependable research.

2.1.3 Health and social care research is not the province of a single discipline, profession or organisation and no single document adequately captures the full range of legislation, standards and guidelines that need to be applied across this wide ranging body of work. They are presented here in five domains:

- Ethics.
- Science.
- Information.
- Health, Safety and Employment.
- Finance and Intellectual Property.

Where available, appropriate website addresses have been included to enable access to the current standards, legislation and guidance listed in the domains. Where these relate to more than one domain they have been cross-referenced.

2.1.4 Each domain has been grouped as follows:

- standards set out in legislation and regulations;
- other standards required by the Department of Health;
- other established standards of good practice from recognised international and national authorities and professional organisations.

2.1.5 The contents of the Annex will be updated regularly. Key and enduring principles in each of the domains are set out in the following paragraphs.

2.2 Ethics

2.2.1 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study. Box A describes a scenario to illustrate good practice in protecting research participants' rights.

Box A Protecting Research Participants' Rights

What does it really feel like to be asked to participate?

The scenario: A Professor of Social Work was awarded a grant by the Department of Health to study support services for adoptive families. The research involved the study of adopted children and their parents. The study included children aged between 8 and 14.

The study also involved a survey of, and interviews with, a sample of adoptive parents. The research team sent the adoptive parents a letter and standard information sheet about the children's study. The information provided aimed to help them come to a decision about whether to support their child's participation in the research. It covered the project aims, interview arrangements, interview topics, and consent and confidentiality. It invited them to discuss over the phone any aspect of the study with the research team.

Enclosed with the parents' letter and information sheet was an information pack for them to pass on to their child. The letter noted that the child might be puzzled by its arrival, and suggested that it might be helpful for them to explain that they have already taken part in the project. Before handing the pack to their adopted child, the parents had some questions about the study that the mother put to the lead researcher over the phone. The researcher clarified that the mother was speaking for herself and the child's adoptive father.

Parent - I've read the information, I think I understand it, but there are a few points I'm not sure about. I think my child may be keen to take part, but I'm worried she might find it upsetting.

Researcher - I can't really say that there's no possibility of something coming up that she may find upsetting. But if your daughter finds a question upsetting she won't have to answer it and she can stop the interview at any time. At the start of the interview we'll help her to rehearse telling us that she doesn't want to answer particular questions or that she doesn't want to go on. In the Information Sheet we noted down some of the topics we want to cover. Is there anything about your daughter's experience that it might be particularly helpful for the interviewer to be aware of?

Parent – No, I can't think of anything, but will you tell me what she says?

Researcher – No, we'll reassure her that whatever she says won't be repeated to you, her teachers, or anyone else she knows. But we'll also let her know that she can tell other people about the interview if she wants to. If she talks about any problems which it seems you or other people aren't aware of, we'll explore whether she wants to talk about them with anybody else and, if appropriate, we'll gently encourage her to do so. In our other research with children we've found that once they've talked about a problem during an interview they're usually quite keen to talk about it with someone else.

Parent - How do I know it'll be worthwhile?

Researcher - At the moment we know very little about children's view of adoption. We particularly need to know if support services need to be improved for adopted children and their families. The study's been commissioned by the Department of Health and the findings will be fed directly into the Government's review of adoption. It has undergone ethical review.

Parent - If she says 'yes' can she pull out later?

Researcher – Yes. She can change her mind whenever she wants. We put that in writing for you and your daughter.

Parent - When the study's finished will you tell us what you've found out?

Researcher - Yes, we'll be writing a summary of our findings especially written for all the families who've taken part.

Parent - Do I have to make my mind up now?

Researcher - No, we don't need to know today, but it would be helpful if we knew by the 20th of next month - that's about four weeks away. Think about it for a while and call me again if you have any more questions.

Scenario: A week or so later the parent decided to pass on the information pack about the study to her eight-year-old daughter. This introduced the research team and explained that they were writing a book about adoption. It also explained the purpose and scope of the interview, and arrangements for gaining their consent and protecting their confidentiality. A few days later the child rang with her own questions:

Child - How long do you want to talk to me?

Researcher - For about an hour, but if you've only a few things to say it could be less than an hour. If you have a lot to say it could take longer.

Child - Will you tell anyone what I say?

Researcher - Only the people we work with at the university.

Child - Will you write down what I say?

Researcher - Maybe, but we'd really like to tape what you say if that's OK with you.

Child - Will anybody reading the book know me?

Researcher - No one will know your name except us.

Child - Will you all come to speak to me?

Researcher - No, just one of us.

Child - Can I change my mind?

Researcher - Yes, of course. You can change it at any time.

Child - What if I'm not sure?

Researcher - Take your time. We don't need to know straightaway. Talk to someone else about it if that helps, but it would be helpful if you could let me know in about three weeks time. If I have not heard from you by 20th, I will take it that you've decided that you don't want to take part.

This researcher is trying to do the right things in the right way. The principles of the research governance framework are reflected in her practice.

- 2.2.2 The Department of Health requires that all research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.
- 2.2.3 Informed consent is at the heart of ethical research. All studies must have appropriate arrangements for obtaining consent and the ethics review process must pay particular attention to those arrangements.
- 2.2.4 Particular care is needed when research involves tissue or organs of the deceased. The consent of their relatives must always be obtained, and it must be recognised that agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives.
- 2.2.5 The appropriate use and protection of patient data is also paramount. All those involved in research must be aware of their legal and ethical duties in this respect. Particular attention must be given to systems for ensuring confidentiality of personal information and to the security of these systems.
- 2.2.6 Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research. Social care research has a long tradition of the involvement of participants in research. The Consumers in NHS Research Group has established the principle that major advisory bodies in NHS R&D programmes should normally have at least two consumer representatives.
- 2.2.7 Research and those pursuing it should respect the diversity of human culture and conditions and take full account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking, and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population.
- 2.2.8 Some research may involve an element of risk to those participating in it. Risk must always be kept to a minimum and explained clearly to the relevant ethics committee and to participants. Arrangements for compensation in the unlikely event of non-negligent harm must always be explained.

2.2.9 Some essential research into important illnesses and treatments can only be conducted with animals. When considering undertaking research which could involve the use of animals, wherever possible, alternatives such as cells, tissues, computers, bacteria, and plants must be used instead. Where animal use is unavoidable, there are strict controls, enforced by the Home Office. Before a researcher can use animals, a series of special licences must be obtained; primates are only to be used if less advanced animals could not provide the information; researchers must have the necessary skills, training and experience, and the research laboratory must have the facilities to care for the animals properly. In addition, there are three principles that should be followed: the replacement of animals by non-animal methods wherever possible; the reduction of numbers to the minimum necessary to obtain valid results where replacement is not possible; and refinement of all procedures to minimise adverse effects. The highest standards of animal husbandry and welfare under veterinary supervision must be maintained at all times and an ethical review process must operate in accordance with Home Office requirements listed in the Annex.

2.3 Science

- 2.3.1 It is essential that existing sources of evidence, especially systematic reviews, are considered carefully prior to undertaking research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.
- 2.3.2 All proposals for health and social care research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for peer review must be commensurate with the scale of the research. For example, many organisations allow established research teams to determine details of the elements of an overall programme of research, which has been reviewed externally. For many student research projects the university supervisor may provide an adequate level of review.
- 2.3.3 Research involving medicines is regulated under the Medicines Act². All trials of new medicinal products on people must be notified to the Medicines Control Agency who can offer advice and who undertake advisory inspections for such trials and the preparation of products used in them. Similarly, research involving new medical devices is regulated by the Medical Devices Agency.

² The Medicines Act, 1968.

2.3.4 Special regulations govern the use of human embryos, the release of genetically modified organisms and food or food processes. Further information is set out in the Annex.

2.3.5 Data collected in the course of research must be retained for an appropriate period to allow further analysis by the original or other research teams subject to consent, and to support monitoring of good research practice by regulatory and other authorities. Guidance on storage is set out in the Annex.

2.4 Information

2.4.1 Health and social care research is conducted for the benefit of patients, users, care professionals, and the public in general. There should be free access to information both on the research being conducted and on the findings of the research, once these have been subjected to appropriate scientific review. This information must be presented in a format understandable to the public. Reports need to be comprehensible and take language and other needs into account.

2.4.2 Some advances in health and social care need to be developed commercially if they are to be made widely available. Drugs, medical devices and aides for the disabled are examples. Successful commercial development often depends upon the protection of intellectual property or commercial confidentiality at critical points in the innovation process. The timing of the publication of research findings needs to take account of this.

2.4.3 All those pursuing health and social care research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made available to those participating in the research (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) and to all those who could benefit from them, through publication and/or other appropriate means.

2.5 Health and Safety

2.5.1 Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants, and of research and other staff must be given priority at all times, and health and safety regulations must be strictly observed.

2.6 Finance

- 2.6.1 Financial probity and compliance with the law and with the rules laid down by H M. Treasury for the use of public funds are as important in research as in any other area.
- 2.6.2 Organisations employing researchers must be in a position to compensate anyone harmed as a result of their negligence. Any organisation offering participants compensation in the event of non-negligent harm must be in a position to do so.
- 2.6.3 Careful consideration must be given to the appropriate exploitation of intellectual property rights as set out in the Annex.

2.7 Quality Research Culture

2.7.1 Some standards set out in the Annex are clear-cut but many require judgement and interpretation. A quality research culture, where excellence is promoted and where there is visible and strong research leadership and expert management, is essential if researchers and managers are to understand and apply standards correctly. A quality research culture is thus essential for proper governance of health and social care research.

2.7.2 The key elements of a quality research culture are:

- Respect for participants' dignity, rights, safety and well-being.
- Valuing the diversity within society.
- Personal and scientific integrity.
- Leadership.
- Honesty.
- Accountability.
- Openness.
- Clear and supportive management.

Promotion of these principles and values is as important as the more detailed standards set out in the Annex.

2.7.3 Box B illustrates how research is managed in a health or social care organisation with a quality research culture.

Box B Standards in a Quality Organisation Undertaking Research

Quality Research Culture

The organisation supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care. There is strong leadership of research and a clear strategy linking research to national priorities and needs, the organisation's business, and to clinical governance (in NHS organisations) and delivery of best value (in social care). The organisation's research strategy values diversity in its patients or users and its staff and promotes their active participation in the development, undertaking and use of research.

Science

There is commitment to the principle and practice of independent peer review, with scrutiny of the suitability of protocols and research teams for all work in the organisation. There is close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work and avoidance of unnecessary duplication of functions.

The organisation's human resource strategy includes commitment to support research careers (full and part-time) by earmarking funds specifically for R&D training across the professions. The organisation plays its role in developing research capacity with appropriate training and updating. This includes taking action to ensure that the diversity of the workforce reflects society and developing the capacity of consumers to participate.

The organisation promotes a high standard of health and safety in laboratory work.

Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research.

The organisation assesses its research outputs and their impact and value for money.

Ethics

All research which involves patients, users or care professionals or their organs, tissue or data is referred to independent ethical review to safeguard the dignity, rights, safety and well-being of the participants.

Research is pursued with the active involvement of service users and carers including, where appropriate, those from hard to reach groups such as the homeless.

If organs or tissue are used following post mortem, informed consent is obtained from relatives, and there is a commitment to respectful disposal of material.

If animal use is unavoidable the highest standards of animal husbandry are maintained under veterinary supervision.

Box B Standards in a Quality Organisation Undertaking Research (Continued)

Information

Information is available on all research being undertaken in the organisation. This is held on a database, which contains details of funding, intellectual property rights, recruitment, research outputs and impact.

The organisation ensures that patients, users and care professionals have easy access to information on research. Special arrangements are made to ensure access to information for those who are not literate in English or who may need information in different formats because of a disability eg braille.

Those agreeing to be involved in research (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) are informed of the findings at the end of the study.

An information service provides access from a single point to all up-to-date regulatory and advisory documentation pertaining to research governance, together with procedural guidance, for example, for applications to research ethics committees.

There is a research dissemination strategy which addresses different media and writing styles for different audiences.

Finance

The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.

The organisation demonstrates financial probity and compliance with the law and rules laid down by HM Treasury. It complies with all audit required by external funders or sponsors and has systems in place to deter, detect and deal with fraud.

When research findings have commercial potential the organisation takes action to protect and exploit them, in collaboration with its research partners and - when appropriate - commercial organisations.

3. Responsibilities and Accountability

3.1 General

- 3.1.1 All those involved in research with human participants, their organs, tissue or data must be aware of and implement the law, and the basic principles relating to ethics, science, information, health and safety, and finance set out in this framework.
- 3.1.2 All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they play in relation to any research. They must be aware of, and have ready access to, sources of information and support in undertaking that role.

3.2 Agreements

- 3.2.1 A complex array of organisations and individuals may be involved in a health or social care research study. It is essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.
- 3.2.2 Organisations that collaborate on a range of research work may find it helpful to develop and document framework agreements to facilitate the agreement of responsibilities for specific studies. Examples of collaborations where framework agreements will be necessary are:
- NHS trusts, primary care practices, groups or trusts and health authorities who work together regularly on research, whether or not in a formal network;
 - universities and NHS trusts, primary care practices, groups or trusts, research networks and health authorities that work together regularly on research;
 - local authorities and/or other social care providers, health authorities and primary care practices, groups or trusts that work together regularly on research whether or not in a formal research network;

- universities, local authorities and other social care providers who work together regularly on research.

3.2.3 It is particularly important that clear and documented agreements are in place for complex studies where there may be:

- work on more than one site; and/or
- researchers employed by more than one organisation; and/or
- patients, users and care professionals from more than one care organisation; and/or
- more than one funder.

3.3 Specific Responsibilities

3.3.1 Box C describes the people and organisations involved in a health or social care research study. The key responsibilities of the people and organisations accountable for the proper conduct of a study are summarised in Box D.

3.3.2 The remainder of this section sets out these responsibilities in more detail. Box E illustrates these responsibilities with a scenario.

Box C Description of the People and Organisations Involved in a Health or Social Care Research Study

- **Participants** - patients, users, relatives of the deceased, professional carers or members of the public agreeing to take part in the study.
- **Researchers** - those conducting the study.
- **Principal Investigator** - the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study.
- **Funder(s)** - organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation.
- **Sponsor** - the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting; the sponsor is usually, but does not have to be, the main funder.
- **Employing Organisation(s)** - the organisation(s) employing the principal investigator and/or other researchers. The organisation employing the principal investigator will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funders are responsible for the management of the funds provided.
- **Care Organisation** - the organisation(s) responsible for providing care to patients and/or users and carers participating in the study.
- **Responsible Care Professional** - the doctor, nurse or social worker formally responsible for the care of the participant while they are taking part in the study.
- **Research Ethics Committee** – the committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards.

Box D Summary of Key Responsibilities of People and Organisations Accountable for the Proper Conduct of a Study

Principal Investigator and other researchers

- Developing proposals that are ethical and seeking research ethics committee approval
- Conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent
- Ensuring participant welfare while in the study
- Feeding back results of research to participants

Research Ethics Committee

- Ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants

Sponsor

- Assuring the scientific quality of proposed research
- Ensuring research ethics committee approval obtained
- Ensuring arrangements in place for the management and monitoring of research

Employing organisation

- Promoting a quality research culture
- Ensuring researchers understand and discharge their responsibilities
- Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor

Care organisation/ Responsible care professional

- Ensuring that research using their patients, users, carers or staff meets the standard set out in the research governance framework (drawing on the work of the research ethics committee and sponsor)
- Ensuring research ethics committee approval obtained for all research
- Retaining responsibility for research participants' care

Box E Specific Responsibilities of Key People Involved in Research

Who is responsible for what ? – some questions and answers

The Scenario: A university Senior Lecturer in General Practice is awarded a grant by the Medical Research Council (MRC) to conduct a trial. The grant is paid to the university but the MRC is closely involved in the development of the trial design, and in the subsequent monitoring of the trial, and the study is based on MRC's General Practice Research Framework. It is agreed that MRC should take on the responsibilities of sponsor. The manufacturer of the drug being trialled has agreed to provide it free. The drug already has a licence. The research is taking place in a number of general practices which have agreed to participate.

PATIENT

Q: I did tell my GP that I might be interested in joining the study, but that does not commit me definitely, does it?

A: Your GP has agreed to join this study and invite her patients to participate. Whether or not you agree is entirely up to you.

Q: How can I know the study is worthwhile?

A: Well the study has been approved as scientifically sound and worthwhile by the Medical Research Council and as ethical by the Research Ethics Committee.

Q: How can I find out more about it?

A: You can take away this patient information leaflet to study, and you can ask your GP or anyone on the research team for further details.

Q: What if the drug involved does not agree with me?

A: Your GP is responsible for your care. She is satisfied with the arrangement to monitor participants in the trial. We will advise her immediately if we detect any problems, and you can approach her at any time.

G.P.

Q: How do I know that this study is well designed?

A: The study is sponsored by the Medical Research Council and has therefore been through their review system, but you must decide whether or not you want to collaborate with it.

Box E Specific Responsibilities of Key People Involved in Research (Continued)

G.P.

Q: Who is responsible for the care of my patients if they agree to take part?

A: You are. The protocol explains the procedures the research team will follow and the circumstances in which they will alert you to anything they observe in your patients. You must ensure you are satisfied with these arrangements and discuss them with the principal investigator if you are not.

Q: Who is responsible for ensuring that the study is conducted according to the protocol and that data are monitored to detect any possible problems?

A: The principal investigator is responsible for ensuring that you and every other person involved in the study is well informed, and able to carry out their roles properly. If you have any concerns about this, you should contact the principal investigator and, if you are not satisfied with the response, you should raise the matter with the research sponsor, which in this case is the MRC.

Q: Who is responsible for the quality of the drugs?

A: The pharmaceutical company supplying the drugs is taking responsibility for their quality.

Q: One of my patients seems much worse since I entered him into the trial. He is keen to continue, but I am concerned. What should I do?

A: You have primary responsibility for the patient's care. If you are concerned that the research is bad for the patient you should advise him to withdraw. You can explain that you will be talking to the researcher and that if the treatment under the project is the cause of his problems this will be very valuable information in itself.

It is very important that you notify the principal investigator of any concerns you have about treatment under the project.

Q: I have agreed to join the study, but a number of my patients are having trouble understanding what they are being asked to take part in and why. It's taking up an enormous amount of time. What should I do?

A: You should talk to the principal investigator about how communications can be improved. If there are still problems you are free to withdraw.

Box E Specific Responsibilities of Key People Involved in Research (Continued)

PRINCIPAL INVESTIGATOR

Q: Who do I report an adverse event to?

A: Any worrying reaction must be reported immediately to the patient's GP. Any adverse drug reaction, as well as reporting it to the patient's GP, must be reported to the drug manufacturer, the Medicines Control Agency, the Trial Steering Committee, the Research Ethics Committee and the Data Monitoring Committee. The Steering Committee will decide whether or not to notify the sponsor.

Q: I am concerned that the staff in the university labs are not following appropriate health and safety rules. What do I do?

A: You should raise this concern through the university's local health and safety systems.

Q: I want to go on a training course, who should I talk to?

A: The university as your employer is responsible for your training.

Q: To whom do I talk about my suspicion that a university colleague is fabricating data?

A: The university as employer has primary responsibility. You should use the university's local system for dealing with suspected misconduct. The sponsor also has an interest. You should keep them informed, particularly if you have any concerns following your approach to the university. They have powers to withdraw funding. You could also consider consulting other organisations such as the General Medical Council with authority to regulate the conduct of the person concerned.

Q: I think we could improve the design of this study. What do I do?

A: You should discuss this with the Trial Steering Committee. If they agree, you will need to draw up a revised protocol and submit it through both ethical review and the MRC's scientific review system. You should not implement changes to a protocol without these formal agreements.

Q: I think I have generated some important intellectual property. What should I do?

A: Ownership of intellectual property will be addressed in your University's contract of employment with you and in their contract with the sponsor. There may also be an agreement between the university and the NHS locally. You need to report the findings to the University's responsible officer, who will advise you on the procedures to be followed.

3.4 Responsibilities of Participants

- 3.4.1 Effective and responsive services depend upon research. Through this framework and related provisions, the Government and its research partners strive to ensure that research conducted in health and social care in England offers the likelihood of real benefits either to those who participate, or those who use services subsequently, or both. All those using health and social care services should give serious consideration to invitations to become involved in the development or undertaking of research studies.
- 3.4.2 Researchers are responsible for selecting appropriate means of communication to ensure that potential participants are fully informed before deciding whether or not to join a study. Potential participants should not hesitate to ask if they do not understand the information and explanations given. Guidance on research with children and others who may have difficulty understanding the information given is listed in the Annex.

3.5 Responsibilities of Researchers

- 3.5.1 Researchers bear the day-to-day responsibility for the conduct of research. They are responsible for ensuring that any research they undertake follows the agreed protocol, for helping care professionals to ensure that participants receive appropriate care while involved in research, for protecting the integrity and confidentiality of clinical and other records and data generated by the research, and for reporting any failures in these respects, adverse drug reactions and other events or suspected misconduct through the appropriate systems.

3.6 Responsibilities of the Principal Investigator

- 3.6.1 A senior individual must be designated as the principal investigator for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data. This person will take responsibility for the conduct of the research and is accountable for this to their employer, and, through them, to the sponsor of the research and to the care organisation(s) within which the research takes place or through which participants, their organs, tissue or data are accessed.

3.6.2 Principal investigators must have suitable experience and expertise in the design and conduct of research so that they are able either to undertake the design, conduct, analysis and reporting of the study to the standards set out in this framework or to lead and manage others with delegated responsibility for some of these aspects.

3.6.3 It is the principal investigator's responsibility to ensure that:

- The dignity, rights, safety and well-being of participants are given priority at all times by the research team.
- The research is carried out in accordance with this research governance framework.
- Controlled trials are registered.
- The Chief Executive of the care organisation(s) involved and/or any other individual(s) with responsibilities within this framework are informed that the study is planned, and that their approval is given before the research commences.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate and agree to retain overall responsibility for their care.
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, that the agency director or her deputy agrees to the person (and/or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Unless participants or the relevant research ethics committee request otherwise, participants' care professionals are given information specifically relevant to their care which arises in the research.
- The study complies with all legal and ethical requirements.
- Each member of the research team is qualified by education, training and experience to discharge his/her role in the study.

- Students and new researchers have adequate supervision, support and training.
- The research follows the protocol approved by the relevant ethics committee and the research sponsor.
- Any proposed changes or amendments to or deviations from the protocol are submitted for approval to the ethics committee, the research sponsor and any other appropriate body.
- Procedures are in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.
- Arrangements are made for the appropriate archiving of data when the research has finished.
- Reports on the progress and outcomes of the work required by the sponsor, funders, or others with a legitimate interest are produced on time and to an acceptable standard.
- The findings from the work are opened to critical review through the accepted scientific and professional channels.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- He or she accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.
- Arrangements are in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising.
- All data and documentation associated with the study are available for audit at the request of the appropriate auditing authority.

3.7 Responsibilities of Research Funders

- 3.7.1 Organisations that fund research, have a responsibility for ensuring that the work is a proper use of the funds they control and provides value for money.
- 3.7.2 Organisations wishing to fund research which requires the collaboration of the NHS or social care services in England must either be willing and able to discharge the responsibilities of research sponsor or collaborate with another organisation which is prepared and able to do so. Potential collaborators include the Department of Health itself and the NHS and/or university bodies to which the Department has delegated authority to act as research sponsor for work within programmes of social care or NHS research funded by the Department or the NHS.

3.8 Responsibilities of Research Sponsor

- 3.8.1 The research sponsor plays a critical role in assuring the quality of research. Any research requiring the collaboration of the NHS or social care services in England must have an organisation willing and able to take on the responsibilities of research sponsor. The responsibilities of sponsor of research undertaken for research training purposes are carried out by the research supervisor.
- 3.8.2 The research sponsor is responsible for assessment of the quality of the research as proposed, the quality of the research environment within which the research will be undertaken and the experience and expertise of the principal investigator and other key researchers involved. They are responsible for ensuring that arrangements are in place for the research team to access resources and support to deliver the research as proposed and that agreements are in place which specify responsibilities for the management and monitoring of research. They are also responsible for ensuring that arrangements are in place to review significant developments as the research proceeds, particularly those which put the safety of individuals at risk, and to approve modifications to the design.
- 3.8.3 The sponsor is responsible for ensuring that arrangements are in place for the management and monitoring of research. In cases where it is inappropriate for the organisation employing the principal investigator or initiating the research to take responsibility for the proper management and monitoring of research, the sponsor should either take that responsibility or agree with another organisation involved that it should take responsibility.

3.8.4 Where research sponsors provide substantial blocks of funding to teams with expertise and track record they may delegate responsibility for specific design and management of research to that team, provided the sponsor manages performance.

3.8.5 Where research has no external sponsor, care organisations must accept the responsibility of the sponsor. For example, an NHS trust must be willing and able to act as the sponsor for research which does not have an external sponsor (sometimes called “own account” research).

3.8.6 It is the research sponsor’s responsibility to ensure that:

- The research proposal is worthwhile, of high scientific quality and represents good value for money
- The research proposal has been approved by an appropriate research ethics committee³.
- Appropriate arrangements are in place for the registration of trials.
- The principal investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources being proposed are those required to allow appropriate data analysis and data protection.
- Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards.
- Arrangements proposed for the work are consistent with the Department of Health research governance framework.
- Organisations and individuals involved in the research all agree the division of responsibilities between them.
- There is a clear written agreement identifying the organisation responsible for the ongoing management and monitoring of the

³ See Section 3.12 for details of research ethics committees. The Department of Health is working to extend the present coverage of committees to review the ethics of social care research. If it is not possible to have a social care research proposal reviewed by an appropriate committee, the sponsor must satisfy itself that the research is ethical.

study, whether this is the organisation employing the researchers, the sponsor, or another organisation.

- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.
- An agreement has been reached about the provision of compensation in the event of non-negligent harm and any organisation, including the sponsor itself, offering such compensation has made the necessary financial arrangements.
- Arrangements are proposed for disseminating the findings.
- All scientific judgements made by the sponsor in relation to responsibilities set out here are based on independent and expert advice.
- Assistance is provided to any enquiry, audit or investigation related to the funded work.

3.9 Responsibilities of Universities and Other Organisations Employing Researchers

3.9.1 Employers of staff undertaking health and social care research have responsibility for developing and promoting a quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This will involve careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from complaints. These responsibilities apply to both private and public sector employers.

3.9.2 Organisations that employ principal investigators and other researchers have responsibility for ensuring that those researchers understand and discharge the responsibilities set out for them in this framework. They should also be prepared to take on some or all of the responsibility for ensuring that a study is properly managed and for monitoring its progress. The nature of the responsibilities taken on by the employing organisation should be agreed with the sponsor and care provider. The sponsor has ultimate responsibility for ensuring that appropriate

arrangements are in place for the management and monitoring of any study they sponsor.

3.9.3 Employers should ensure that agreements are in place between them and their staff and between them and research funders and care organisations about ownership, exploitation and income from any intellectual property that may arise from research conducted by their employees. They have a responsibility for ensuring that employees identify and protect intellectual property.

3.9.4 Universities and other employers of staff engaged in research are responsible for:

- Compliance with all current employment and health and safety legislation.
- Demonstrating the existence of clear codes of practice in other areas for their staff and mechanisms to monitor and assess compliance.
- Ensuring that the principal investigator and/or other research staff are aware of, understand and comply with this framework.
- Discharging their agreed role in the management and monitoring of work undertaken by their organisation.
- Demonstrating systems for continuous professional development of staff at all levels.
- Having agreements and systems in place to identify, protect and exploit intellectual property.
- Ensuring that they are able to compensate anyone harmed as a result of negligence on the part of their staff and, if they have agreed to do so, for non-negligent harm arising from the research.
- Having in place systems to detect and address fraud, and other scientific or professional misconduct by their staff.
- Having in place systems to process, address and learn lessons from any complaints brought against their employees.
- Permitting and assisting in any investigation arising from complaints received in respect of actions taken by their employees.

3.10 Responsibilities of Organisations Providing Care

- 3.10.1 All organisations providing health or social care in England must be aware of all research being undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation. They should ensure that their patients, users and care professionals are provided with information about any research which may have a direct impact on their care, their experience of care, or their work in the organisation. They must ensure that only activity which is being managed formally as research within the provisions of this framework, is presented as research.
- 3.10.2 Organisations providing care are responsible for ensuring that any research involving their patients, users and carers or staff meet the standards set out in this framework, in particular that it has an identified research sponsor willing and able to discharge its responsibilities, and that clear and documented agreements are in place about the allocation of responsibilities between all parties involved. Accountability for this lies with the Chief Executive or Agency Director but he or she may delegate responsibility for ensuring compliance to an appropriately qualified and senior member of staff. The care provider remains responsible for the quality of all aspects of the care of their patients or users, whether or not they are involved in research and whoever that research may be conducted and funded by.
- 3.10.3 Chief Executives of NHS organisations are accountable for quality under the Duty of Care. Researchers not employed by the NHS organisation who interact with individuals in a way which has direct bearing on the quality of their care should hold an NHS honorary contract. Further guidance on issues of employment and accountability of university staff working in the NHS will be issued when a review of these areas led by the Department for Education and Employment reports.
- 3.10.4 A summary of the main responsibilities of organisations providing care are to:
- Retain responsibility for the quality of all aspects of participants' care whether or not some aspects of care are part of a research study.

- Be aware and maintain a record of all research work being undertaken through or within the organisation, including research undertaken by students as part of their training.
- Ensure patients or users and carers are provided with information on research that may affect their care.
- Be aware of any current legislation relating to research work and ensure that these are implemented effectively within the organisation.
- Ensure that all research has been approved by an appropriate research ethics committee.⁴
- Ensure that all research has an identified sponsor who understands, accepts and is able to discharge their duties as set out in this framework.
- Ensure that written agreements are in place regarding responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with the University or other employer in relation to student supervision.
- Ensure that the necessary links with clinical governance and best value processes are made.
- Ensure that non-NHS employed researchers hold honorary NHS contracts where appropriate and that there is clear accountability and understanding of who is responsible for what.
- Put in place and maintain the necessary systems to identify and learn from errors and failures.
- Put in place and maintain the necessary systems to process, address and learn lessons from complaints arising from any research work being undertaken through or within the organisation.
- Ensure that significant lessons learnt from complaints and from internal enquiries are communicated to funders, sponsors and other partners.
- Permit and assist with any monitoring, auditing or inspection required by relevant authorities.

⁴ See footnote to paragraph 3.8.6

3.11 Responsibilities of Care Professionals

- 3.11.1 Health and social care staff retain responsibility for the care of their patients or users, when they are participating in research.
- 3.11.2 Before agreeing to their patients or users being approached, they must satisfy themselves that the research has been the subject of approval by appropriate scrutinising authorities within their organisation or agency, and that any research that relates directly to the care they provide complies with this framework.

3.12 Responsibilities Relating to Research Ethics Committees

- 3.12.1 Those establishing research ethics committees should ensure that the committees:
- have clearly defined remits and terms of reference that are consistent with the system of ethics committees established through the powers of the Secretary of State for Health;
 - have clearly defined arrangements for appointing and replacing members;
 - have and meet clear performance targets;
 - are adequately resourced, supported and trained;
 - provide clear and independent advice, within their remit and terms of reference.
- 3.12.2 Research ethics committees and their members must act in good faith and provide impartial and independent advice within their remits and terms of reference. Their primary responsibility is to ensure that the research respects the dignity, rights, safety and well-being of individual research participants. They should also work efficiently to facilitate the good conduct of high quality research that offers benefits to participants, services and society at large. Unjustified delay to such research is itself unethical.

- 3.12.3 Research within the NHS, which involves individuals, their organs, tissue or data must have the prior approval of an NHS research ethics committee. The NHS is responsible for establishing, supporting and monitoring the performance of NHS research ethics committees (RECs). Those outside the NHS may also seek the advice of these committees.
- 3.12.4 Whilst operating within a Department of Health and NHS management framework, RECs must maintain independence when formulating their advice on the ethics of the proposed research if their advice is to be seen to be impartial. NHS research ethics committees are managerially independent of NHS Trust R&D structures.
- 3.12.5 Social care research involving work in NHS settings must be approved by the relevant NHS REC. For other social care research, the Association of Directors of Social Services (ADSS) Research Group advises the ADSS and individual directors and social services departments on the ethics, quality and relevance of proposals for multi-site studies. The Department of Health is discussing with ADSS how arrangements could best be developed to provide a more comprehensive system for the ethical review of social care research. Meanwhile, a number of universities run ethics committees which may be able to advise on social care research studies, and sponsors should take responsibility for ensuring that work is ethical when there is no appropriate committee to review it.
- 3.12.6 The decision on whether or not research in an NHS organisation should ultimately proceed rests with that organisation. No research should proceed without prior REC approval. However, even though REC approval may have been obtained, an NHS organisation may need to consider other factors before permitting the research to proceed. Similarly, Directors of Social Services are responsible for approving social care research conducted within their local authorities.
- 3.12.7 It is not the role or responsibility of the research ethics committees described above to give legal advice, nor are they liable for any of their decisions in this respect. Irrespective of the decision of a research ethics committee on a particular application, it is the researcher and the NHS or social care organisation who have the responsibility not to break the law. If a research ethics committee

is of the opinion that implementation of a research proposal might contravene the law, it should advise both researcher and the appropriate authority of its concerns. The researcher and the organisation will need then to seek legal advice.

- 3.12.8 NHS research ethics committees require researchers working in the NHS to keep them informed of the progress of a study. Research ethics committees are responsible for reviewing their advice on the ethical acceptability of a study in the light of such information. However, the principal investigator and his or her employer, the research sponsor and the care organisation, and not the research ethics committee, are responsible for ensuring that a study follows the agreed protocol and for monitoring its progress.

4. Delivery Systems

- 4.1 Organisations undertaking, sponsoring, funding or hosting health and social care research must have systems in place to ensure that they and their staff understand and follow the standards and good practice set out in this framework.
- 4.2 All research sponsors must have systems in place, or have access to systems to undertake expert independent review - appropriate to the scale and complexity of research proposals - to allow the organisation to satisfy itself on the scientific and ethical standing of the work, its strategic relevance and value for money. They must also ensure that systems are in place - managed either by themselves or by one of the organisations involved in the research, such as the host university, a funding body, or care provider - to ensure that all research they sponsor is conducted according to the agreed protocol, to monitor its general progress and to discuss and agree modifications to the protocol if the need arises.
- 4.3 All health and social care providers must have systems in place to ensure that they are aware of, and have given permission for, all research being conducted in or through their organisation, whether or not it is externally funded. Care providers should only give permission for research which has a sponsor. Care providers may only themselves take on the role of sponsor if they have systems in place to discharge those responsibilities. Whoever acts as sponsor, care providers must satisfy themselves that systems are in place, either in their own organisation or elsewhere, to ensure that all research conducted in or through their organisation conforms to appropriate scientific and ethical standards, and offers value for public money.
- 4.4 All those establishing research ethics committees must have systems in place to convene, support and monitor the performance of research ethics committees.
- 4.5 All research ethics committees should have systems in place to identify, and record and address conflicts of interest that may compromise, or be seen to compromise, the independence of their

advice. They must also have systems in place to record their decisions and the reasons for them, and to record operational details of their meetings and handling of applications. References to formal guidance on this are in the Annex.

- 4.6 All delivery systems should be designed to detect failures to adhere to requirements, regardless of whether such failures arise by intent or oversight. Such systems should involve routine and random monitoring and audit as appropriate. Additionally, delivery systems should require, facilitate and support reporting of critical incidents, near misses, systems failures and misconduct either by self-reporting or whistle-blowing.
- 4.7 The Department of Health will work with key stakeholders to develop and issue guidance from time to time to help organisations discharge their responsibilities for research governance effectively and efficiently. This will cover both systems in individual organisations and systems for agreeing and discharging responsibilities between two or more organisations, e.g. a care provider and a university, or a number of care providers in a multi-centre study. Initial guidance will focus on the most important and challenging areas. Early attention will be given to guidelines on arrangements for studies involving the use of organs, in consultation with the Retained Organs Commission.
- 4.8 Regional Offices of the Department of Health will work with NHS providers to ensure that they understand their responsibilities, have systems in place to discharge them and take account of relevant guidance. Arrangements for social care will be developed as part of the implementation of the new quality framework outlined in *A Quality Framework for Social Care*.
- 4.9 Research governance depends critically on research workers and research managers understanding their responsibilities and having the skills needed to discharge them. The Department of Health will work with other research funders and the universities to promote the coverage of research governance in relevant degree courses and continuing education for these groups.
- 4.10 There is much good practice in research and many opportunities for individuals and organisations to learn from one another. The Department of Health will promote the development of learning networks to support this. The NHS R&D Management Forum is a good example of such a network.

5. Monitoring, Inspection and Sanctions

- 5.1 Organisations and individuals must be able to demonstrate adherence to this framework to reassure patients, service users and care professionals of the quality of their services and to assure their reputation in high quality research and care.
- 5.2 There are already powerful incentives to adhere to many of the principles and standards set out in the framework. These include the law, the duties of care in the NHS and social care and the high professional and ethical standards upheld by the majority of care professionals and researchers. Mechanisms, which monitor the quality of clinical work, such as audit, risk management and staff appraisal can assist in the monitoring of research governance. Nevertheless, a coherent system is needed to monitor performance against this framework, to identify best practice and shortfalls, to enhance public confidence and help to prevent adverse events. Where minimum acceptable standards are not met, sanctions are needed. The Department of Health will work with its partners to develop a coherent system for monitoring research governance and addressing shortcomings.
- 5.3 New arrangements will be established to work with and through structures, which already exist in health and social care systems, government departments, the universities and the charities to promote and monitor quality. These arrangements will be robust and will monitor the extent to which the standards set out in this framework are being followed by:
 - sponsors of research (including the Department of Health);
 - health and social care organisations participating in
 - universities and other organisations employing researchers;
 - other organisations on which this framework depends.

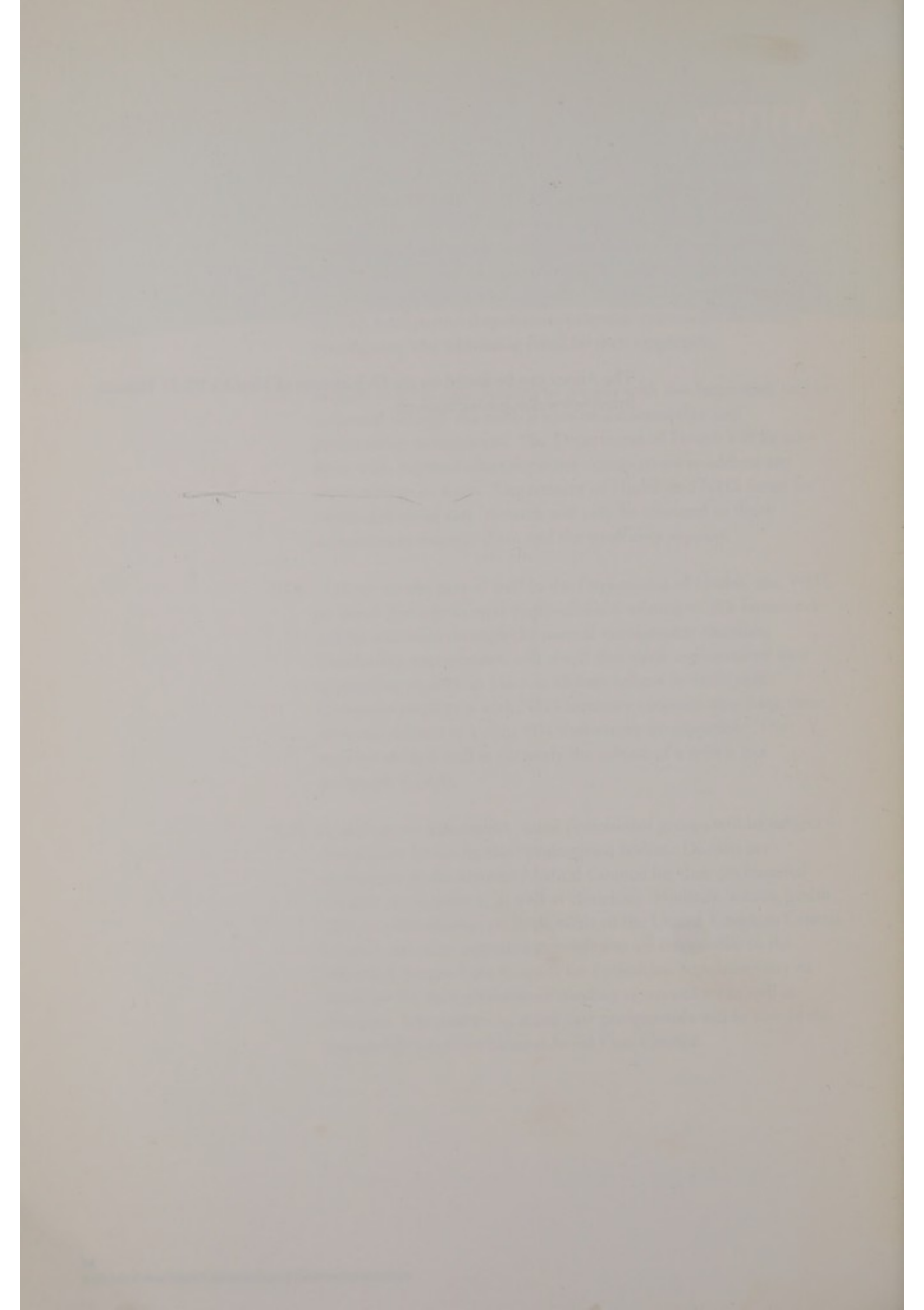
- 5.4 Reports of this monitoring will be presented to the Secretary of State for Health, to the organisations monitored and to those with responsibilities for these organisations. Organisations failing to meet expected standards will be required to produce recovery plans for agreement and implementation.
- 5.5 Under the new arrangements a list of recognised sponsors of health and social care research will be maintained. Health and social care organisations can consult this list to ascertain the standing of those wishing to fund research in their organisation. Research funders and research organisations may apply to be included in the list, subject to them providing a satisfactory account of the adequacy of their systems.
- 5.6 Clinical trials of medicinal products on patients must continue to be notified to the Medicines Control Agency (MCA). New regulations to be introduced in compliance with a proposed European Directive on the conduct of clinical trials will require all trials of medicines to be subject to inspection by the MCA. The Agency offers advisory inspections now against relevant good clinical practice and good manufacturing practice guidelines, in advance of the statutory requirement. Similar arrangements apply to medical devices and are the responsibility of the Medical Devices Agency (MDA). The arrangements described above for monitoring research governance will work closely with the MCA and the MDA to avoid duplication and to share best practice.
- 5.7 The Chief Medical Officer's expert group on learning from adverse events in the NHS reported on ways in which the NHS can learn more effectively from adverse health care events, so that recurrence can be prevented. It has made a number of recommendations, including the establishment of a new national system for reporting adverse health care events and "near misses". Monitoring of research governance will work alongside the new national system for adverse events in the NHS and existing systems for adverse events reporting in social care.
- 5.8 There is growing public and professional concern about research misconduct and fraud, though its extent is unknown. The Department of Health will continue to work with others on research misconduct, including consideration of the possibility of a co-ordinating group or body to take responsibility for investigation on behalf of all relevant stakeholders. The Director of Counter Fraud Services has overall responsibility for all work to counter fraud and

corruption within the NHS. Monitoring of research governance will check that appropriate systems are in place to detect and investigate possible fraud and to take appropriate action if fraud is found. In addition, health and social care organisations should themselves ensure that universities and any other organisations with whom they develop local partnerships have appropriate systems for detecting, investigating and addressing fraud by their employees.

- 5.9 Failures in NHS organisations to comply with this framework will be addressed through the normal lines of accountability and performance management. The Department of Health will look to those with responsibilities for other organisations to address any shortcomings in them. Department of Health and NHS funds for health and social care research will only be allocated to those competent to manage them and the work they support.
- 5.10 Failures on the part of staff in the Department of Health, the NHS or Social Services to meet responsibilities relating to this framework will be addressed through the normal management channels. Monitoring arrangements will check that other organisations have appropriate systems in place to address failures by their staff. University employees with NHS honorary contracts may have these removed, subject to a joint NHS/university investigation. The position of such staff is currently the subject of a review (see paragraph 3.10.3).
- 5.11 In the case of misconduct, some professional groups will be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers, as well as clinicians. Similarly, nurses, health visitors and midwives are responsible to the United Kingdom Central Council and state registered practitioners are responsible to the individual board of the Council for Professions Supplementary to Medicine for their professional conduct as researchers as well as clinicians. Misconduct by social care professionals will be one of the responsibilities of the General Social Care Council.

Annex

The Annex can be found on the Department of Health's R&D Website
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